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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/707,576	11/06/2000	Charles L. Magness	55382-3	9656
22504	7590	04/08/2005	EXAMINER	
DAVIS WRIGHT TREMAINE, LLP 2600 CENTURY SQUARE 1501 FOURTH AVENUE SEATTLE, WA 98101-1688			COLON, CATHERINE M	
			ART UNIT	PAPER NUMBER
			3623	

DATE MAILED: 04/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	<b>Application No.</b> 09/707,576	<b>Applicant(s)</b> MAGNESS ET AL.	
	<b>Examiner</b> C. Michelle Colon	<b>Art Unit</b> 3623	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 28 March 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: see attached. (See 37 CFR 1.116 and 41.33(a)).


4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 1-10, 14-26, 28 and 31-55.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.

  
TARIQ R. HAFIZ  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3600

### ADVISORY ACTION

This Advisory Action is in response to the After Final Amendment and Response submitted on March 28, 2005. The proposed Amendment will not be entered since it raises new issues that would require further search and consideration. In particular, the amendments introduce the following new language, "whose unaffected status is inconsistent with their historic risk factors." Additionally, the amendments do not appear to be the same amendments Applicant submitted in a proposed amendment faxed on February 25, 2005 in an Interview Request Form, which Examiner had indicated in a voicemail left for Applicant's representative that the amendments were more in line with the invention as discussed in the specification.

At issue, is that Applicant argues the invention does not predict *future* risk, however, the very definition of risk connotes a probability, which is associated with a possibility *in time*. For example, the references used during the prosecution history teach identifying individuals at "high risk" for contracting a disease based on medical histories and medical test results. It can be argued that individuals who have been medically identified as "high risk" for contracting a disease do not currently have the disease but by all accounts should have the disease (i.e., individuals identified with a 99% chance of contracting a disease), thus blurring the line between "future risk" versus "current risk." Additionally, the claims, as currently recited, do not expressly indicate how the populations are classified as ARA or ARU (i.e., identifying a trait consistent with

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having a disease). Rather, the claims broadly recite classifying populations “based on” data “related to” medical histories and medical test results.

Examiner has carefully reviewed the After Final Remarks as well as the Specification and suggests wording similar to page 14 of the current Remarks in which Applicant states, “...ARU... is intended to define individuals that ought to be affected by the biological condition at the present time, but for some unidentified factor that prevents them from being presently affected by the biological condition,” in combination with wording on page 6 of the Specification that states, “ those apparently resistant individuals who have been exposed to significant risk but have failed to contract the disease,” to better recite Applicant’s invention and to obviate the “future risk” versus “current risk” dilemma.

The proposed Amendment will not be entered and claims 1-10, 14-26, 28 and 31-55 stand rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Michelle Tarae (formerly, C. Michelle Colon) whose telephone number is 703-605-4251. The examiner can normally be reached Monday – Friday from 8:30am to 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tariq Hafiz, can be reached at 703-305-9643.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1113.

Any response to this action should be mailed to:

***Commissioner of Patents and Trademarks***

***Washington D.C. 20231***

or faxed to:

703-872-9306	[Official Communications; including After Final communications labeled "Box AF"]
703-746-7202	[For status inquiries, draft communication, labeled "Proposed" or "Draft"]

Hand delivered responses should be brought to Crystal Park 5, 2451 Crystal Drive, Arlington, VA 7<sup>th</sup> floor receptionist.



CMC  
April 4, 2005